

Remarks

Entry of the foregoing and reconsideration of the application identified in caption as amended, pursuant to and consistent with the Rules of Practice in Patent Cases, and in light of the remarks which follow, is respectfully requested.

By the present amendment, claims 1-4 have been amended and new claim 13 has been added, so that claims 1-13 will be pending upon entry of the present amendment.

Claims 1-12 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 1-4 state “substantially healthy human skin” which is said not to find support in the instant specification. This rejection is respectfully traversed in light of the deletion of the phrase “substantially healthy” from claims 1-4. Withdrawal of the record rejection is respectfully requested.

Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The term “substantially” is said not to be defined by the claim and the specification is said not to provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This rejection is respectfully traversed in light of the deletion of the phrase “substantially” from claims 1-4. Withdrawal of the record rejection is respectfully requested.

Claims 1-4, 7, 8, 11 and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by either of Raisfeld (US 4,507,321) or Charonis et al. (WO 94/12464). Claims 3, 4, 7, 8, 11, and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Ilenchuk et al. (WO 99/51213); or Minoshima et al. (JP 07/268,323). Claims 3, 4, 8 and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by either of Eckart et al. (EP 0,884,046); Wolf et al. (WO 98/06376); or Matsubara et al. (JP 2003/113047). Claims 1-4, 8, and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hahn et al. (WO 96/23490). These rejections are respectfully traversed.

The claims of the present invention have been amended and relate to a composition and method for the cosmetic treatment of the human skin to improve hydration of the human skin and to maintain the beauty thereof. None of the cited prior art relates to a method of cosmetic treatment of the human skin to improve hydration of the human skin to maintain the beauty thereof.

Moreover, the experimental evidence reported in the specification shows that such effect of the hydration, as measured by a corneometer, is achieved. The corneometer is an instrument for measuring stratum corneum moisture, that is the hydration of the outermost layer of the skin. It measures the electrical capacitance of the skin surface as an indicator of stratum corneum hydration. The corneometer results in the study showed an increase in skin hydration with a statistically significant difference between the mean values observed after treatment and the corresponding values observed after the placebo. The degree of hydration, determined by electric capacitance measured with the corneometer, increased by over 10% with a high statistical significance ($p < 0.001$). Further, the Rinaldi Declaration previously submitted shows that such effect of hydration is not obvious in view of a cell renewal effect as described by the prior art.

None of the cited documents describe or suggest that spermine and/or spermidine in free or salified form can be active as cosmetics inasmuch as they are able to withhold water at the stratum corneum of the epidermis, so that they can improve hydration of the human skin to maintain beauty in any subject.

In contrast, all of the cited prior art documents relate to the treatment of skin of a subject suffering from a pathological disorder or having damaged skin for cell regeneration processes in pathological or damaged skin. This is particularly the scope of Raisfeld, Charonis and Ilenchuk.

As the Examiner notes, such prior art indicates that polyamines can stimulate or inhibit epithelial cell growth. This is a very broad indication indeed, which cannot provide any teaching about improving hydration for cosmetic purposes.

Furthermore, for instance, Raisfeld indicates that treatments of skin disorders are always concerned, such as wound healing, treating burns, treating ischemic, decubitus and peptic ulcers, plastic and reconstructive surgery, dermatological disorders, the treatment of psoriasis and retardation of fibrosis after injuries to the spinal cord and nervous system.

Neither novelty nor obviousness of the cosmetic treatment of instant claim 1 can be reasonably objected on the preceding teachings: a method of cosmetic treatment to improve hydration of the skin to maintain beauty is not made known or obvious by prior art describing a therapeutical treatment of pathological or damaged skin based on cell renewal or possibly even cell inhibition.

Hahn is also cited against the novelty of claims 1 and 2 but does not relate to cosmetic treatment of human skin, rather it relates to animals for inhibiting skin irritation.

Moreover, it should be noted that, referring to the method of treatment claims 1 and 2, the Examiner mentions on page 6 of the office action an alleged inherent effect, by concluding “*The discovery of an unappreciated property...does not render the old composition patentably new...*”. Applicants note that this appears to be a mistake since claims 1 and 2 are concerned with a method of treatment, not a composition. Rather, a cosmetic treatment for maintaining the beauty of the skin through optimal hydration is self-applied by a subject, in contrast to treating burns, treating ischemic, decubitus and peptic ulcers, plastic and reconstructive surgery, is a therapeutical treatment, which is prescribed by a physician. Thus, these treatments are well distinguished.

As to the composition claims 3-12, prior art such as Raisfeld, Charonis, and Ilenchuk, describe that polyamines can both stimulate and inhibit epithelial cell growth. Such a disclosure cannot provide any teaching about improving skin hydration for cosmetic purposes, as confirmed by the expert Rinaldi. Eckart shows how to enhance the photo protective activity of the active principles vitamins C and E on the skin irradiated with UV. Polyamines are only enhancers. Accordingly, the hydration improvement on non-irradiated skin resulting from the clinical study in the present application is therefore a different effect, as again explained in Dr. Rinaldi's Affidavit.

Furthermore, it should be pointed out that claim 6, which refers to the main composition claim 3, describes a range of 0.25 - 0.5 mg of spermidine trihydrochloride, which - by calculation - corresponds to approximately 0.02 - 0.04 % of free spermidine in an oral administration unit (such as the tablets of the examples). Example 10 of Raisfeld describes a capsule with 50 mg of spermidine, which amounts to 16.6% b.w. of that capsule.

The use of such tablet is the same as the use indicated for Example 9 of Raisfeld, i.e., “to treat various injuries and disease states in which an oral route of administration is desirable, e.g., peptic ulcers, burns and trauma, and inflammatory bowel diseases such as ulcerative colitis.”

On the other hand, Examples 1 and 2 of the present application describe a tablet for oral administration containing 0.25 mg of spermidine trihydrochloride, which amounts to 0.14 mg of free spermidine in the tablet, i.e., about 0.021% b.w. of free

spermidine in the tablet. This is a concentration almost 800 times lower than that disclosed in Raisfeld.

Therefore the above range as taught by the instant application cannot be made known or suggested by the oral use of spermidine at a definitely higher concentration in a single oral administration unit to cure diseases, such as peptic ulcers and colitis.

Withdrawal of the record rejections of Claims 1-4, 7, 8, 11 and 12 under 35 U.S.C. § 102(b) is respectfully requested.

Claims 5, 6, 9, and 10 stand rejected under 35 U.S.C. § 103 as being obvious over Minoshima et al. (JP 07/268323) in view of Henderson (WO 00/37087) and Ioannides (WO 02/15860). This rejection is respectfully traversed.

Regarding non obviousness, the previously submitted sworn statement of Dr. Rinaldi shows on the one hand that the above property as studied and claimed in the application in question, i.e., the capability of spermine and/or spermidine of withholding water at the stratum corneum of the epidermis, is not implicit to a person skilled in the art in what is expressly mentioned in the cited documents which concern cell regeneration processes in pathological or damaged skin.

It also shows on the other hand that such property studied and discussed under the clinical study "Assessment of hydration" in the description, i.e., the capability of spermine and/or spermidine of withholding water at the stratum corneum of the epidermis, is not predictable or evident to a person skilled in the art from the cited documents which concern cell regeneration processes in pathological or damaged or affected skin.

It should be furthermore considered that — inasmuch as this property of withholding water at the stratum corneum of the epidermis is concerned -spermine and spermidine are a selection made by the Applicants from a wide range of polyamines. There is no indication in the prior art about any selection in the polyamines to provide a special property which is not simply and broadly cell renewal in pathological or damaged skin.

Accordingly, it would not have been obvious to pick and choose components from the disclosure of three different references to arrive at the claimed invention. Withdrawal of the record rejection of Claims 5, 6, 9, and 10 under 35 U.S.C. § 103 as being obvious over Minoshima et al. (JP 07/268323) in view of Henderson (WO 00/37087) and Ioannides (WO 02/15860) is respectfully requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is hereby earnestly solicited.

Respectfully submitted,

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